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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,194	10/28/2003	Denis Francois Hochstrasser	108140.00030	4418

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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
09/04/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

NYIPDocket@arentfox.com
Patent_Mail@arentfox.com

Office Action Summary	Application No.	Applicant(s)	
	10/695,194	HOCHSTRASSER ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-6,8-11,13,15-17,29-31 and 48-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-6,8-11,13,15-17,29-31 and 48-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 June 2009 has been entered.

Claims 1, 2, 5, 10, 11, 13, 15, 17, 29, 30 and 31 have been amended. Claims 3, 12, 14, 18-28, 32-38 and 40-47 have been canceled. New claims 48-61 have been added.

2. Claims 1, 2, 4-6, 8-11, 13, 15-17, 29-31 and 48-61 are pending and under consideration.

Examiner's Notation

3. It is noted that newly added claims 48 and 59, though listed as "New", contain designations of amendment in line 15, i.e., deletion of the word "and".

In order to expedite prosecution, the examiner is examiner the claims as though the word "and" is absent. However, the correct form of the claims is required with applicants' next response.

Rejections Moot or Withdrawn

4. The rejection of claims 3, 12, 14, 18, 19, 21, 22, 32-38, and 40-46 under 35 U.S.C. 112, first paragraph, scope of enablement for differentiation of any/all forms of TSE by mere alteration of level of nonspecified proteins, is moot in light of the cancellation of the claims.

5. The rejection of claims 29-31 under 35 U.S.C. 112, second paragraph, as being indefinite for identity of "probe", is withdrawn in light of the amendment of the claims.

Rejections Maintained

6. The rejection of claims 1, 2, 4-6, 8-11, 13, 15-17 and 29-31 under 35 U.S.C. 112, first paragraph, scope of enablement for differentiation of any/all forms of TSE by mere alteration of level of nonspecified proteins, is maintained for reasons of record.

Applicants argue that one skilled in the art would understand that there are no specific "cut-off values for discriminating between diseases and healthy patients", and that the differences need only be "significant". Thus, no absolute threshold is applied or required in order to carry out the methods or use the test kits of the presently-claimed invention.

The examiner has considered applicants' arguments, but does not find them persuasive for the reasons put forth in the original rejection. Applicants argument concerning differences being "significant" are directed to an aspect not in claims 1, 2, 4-6, 8-11, 13 and 15-17. In claims 29-31, while reciting that the increase is "significant", there is no definition of what constitutes a "significant" increase.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 48-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific increase/presence/absence/decrease of specified proteins for specific TSE diseases, does not reasonably provide enablement for scope of the instant claims. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention is a method of diagnosis of any/all TSE comprising subjecting a sample of CSF, blood, plasma, or serum from a subject to mass spectrometry, thereby determining the amount of a polypeptide in the sample, comparing the amount to that observed in normal CSF, blood, plasma, or serum, wherein an increase or decrease in the polypeptide in the subject's body fluid compared to the reference indicates any/all TSE in the subject.

The state of the prior art as recited by applicants' own specification indicates that the claimed methods of determining new non-invasive TSE markers in body fluids accompanying new methods of determining the markers do not exist.

The predictability or lack thereof in the art indicates that diagnosis of any/all TSE using specific protein profiles in the CSF, blood, plasma, or serum of TSE patients is uncertain.

The amount of direction or guidance present in the instant specification is not commensurate with the scope of the instant claims. The working examples provided by the instant specification shows that very specific profiles are indicative of CJD and BSE. However,

since there is no comparison of samples with any other disease states, it is unclear how specific the profiles are for either CJD or BSE. The instant specification does not show that the mere increase/presence/absence/decrease of specified proteins is indicative for all TSE diseases. For example, for CJD the profile is as follows:

Profiles positive for CJD compared to normal levels

1) decrease in values – 3295, 3970, 3976, 3990, 3992, 4294, 4300, 4315, 4436, 4478, 4484, 8936, 9107, 9145, 9185, 9454, 10068, 10075, 11730, 13550, 14043, 17809, 17839

2) increase in values – 7574, 7770, 7773, 7930, 7975, 8020

The polypeptide profiles positive for BSE compared to normal levels also varied by whether mere increase/presence/absence/decrease of specified proteins is indicative of BSE, and this is not the same profile as that of CJD levels.

Thus, the quantity of experimentation necessary to fulfill the broad scope of the instant claims, i.e., that any/all forms of TSE can be differentiated from any/all other diseases or can be diagnosed by determining that a mere increase/presence/absence/decrease of nonspecified proteins, constitute merely an invitation to experiment without a reasonable expectation of success.

8. Claims 1, 2, 4-6, 8-11, 13, 15-17, 29-31 and 48-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method of diagnosis of a TSE by comparing the presence of a polypeptide, designated only as having a molecular weight of about a listed daltons, in a sample from a subject suspected of having BSE, vCJD or CJD to a reference amount of the polypeptide in a sample of a non-infected subject.

Because the polypeptide is only designated as having a molecular weight of about one from a list, it is unclear how one distinguishes actual BSE, vCJD or CJD from any other disease state which presents polypeptides of the same molecular weight. For instance, Pat. No. 6,416,962, claims that the presence of one or more polypeptides with molecular weight of about those listed in the instant claims, is indicative of infection with *M. tuberculosis*.

If one detects these *M. tuberculosis* polypeptides, how do you distinguish this infection from actual BSE, vCJD or CJD?

Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

September 2, 2009